ΛTENTIV.

Position Background

Atentiv develops personalized digital learning tools for children that naturally optimize, remediate, or rehabilitate inattention to improve academic performance and symptoms of ADHD. The Company is seeking a Manager of Quality Assurance with experience in the medical device industry and with extensive knowledge performing their function within the Food & Drug Administration (FDA) Quality System Regulations (QSRs), International Organization of Standardization (ISO) 13485:2003, Medical Device Directive (MDD) 93/42/EEC, ISO 14971:2007.

The Manager Quality Assurance will report directly to the COO and will work closely within project teams (and in some cases independently) contributing technical leadership/knowledge in the testing and evaluation of ATENTIV products. This position will contribute to the review of design choices with project management, software architects, software engineers and other quality staff while developing test plans and test cases. This position will interact with project management, software engineers and other technical/support staff on a regular basis. Responsibilities will include, but not be limited to the following:

- Implementing and maintaining Quality Management System (QMS), that complies with ISO 13485, ISO 14971 and FDA 21 CFR Part 820
- Develop, administer and maintain quality assurance procedures and activities required to ensure that the company's processes and products are in compliance with applicable quality standards and requirements
- Design, implement, execute, and manage test plans, test cases and test results for ATENTIV products.
- Develop test scripts and execute test automation as needed
- Root cause analysis and implementation of corrective action for process related concerns.
- Interface with Engineering,Operations and Product Management to design and implement appropriate verification methodology and documentation supporting release of products (alpha, beta, final)
- Support the quality inspection to ensure projects, products and processes comply with the relevant requirements of the QMS
- Analyze failure, corrective and preventive action to respond to internal/external customer complaints.

- Create and maintain company quality documentation, such as manuals, procedures, etc.
- Continuously improve QA processes and procedures.
- Preparation of QA reports.
- Preparation of documentation for submission to FDA for medical device approval and/or response to FDA inquiries.

Education/Experience:

- Minimum BS/BA in computer technology or a science discipline
- 7+ years of experience implementing test strategies, test plans and test cases for software validation and verification in FDA-compliant medical device industry
- Demonstrated success in a start-up, entrepreneurial work environment
- Thorough knowledge of FDA Quality System requirements, ISO 13485:2003 (Quality System) requirements, ISO 14971 (Risk Management) requirements, Medical Device Directives (MDD) requirements, Knowledge of Good Manufacturing Practices (GMP) and applicable Quality System Standards
- Familiar with EN 60601, Safety requirements for medical electrical systems
- Familiar with ISO 62304, Medical Device Software – Software Life Cycle processes
- 5+ years of experience in verification/validation of web-based client/server products incorporating scalable data acquisition, processing, management, and reporting functionalities.
- 4 or more years of experience with QMS implemention that complies with FDA 21 CFR Part 820, ISO 13485 and ISO 14971 standards
- Lead role (administrative or technical) in one or more FDA submissions for approval of a medical device
- Lead role (administrative or technical) in one or more FDA audits for review of a medical device
- Experience with automated tools supporting regression and load testing.
- Experience with Microsoft-based tools.
- Project management skills and proficiency and analyzing and interpreting test data